91. The first stage of the Medicare program, from May 2004 through December 2005 permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program. In addition, low-income beneficiaries, defined as those whose incomes are not more than 135 percent of the poverty line (those with incomes of no more than $12,569 for a single person or $16,862 for a married couple in 2004) qualified for a $600 credit (funded by Medicare) on their drug discount card for 2004, and again for 2005.

92. Section 303© of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303© of the MMA amended Title XVIII of the Act by adding section 1847A, which established a new average sales price (ASP) drug payment system. Beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the ASP methodology, and payment to the providers will be 106 percent of the ASP. There are exceptions to this general rule which are listed in the Medicare Claims Processing Manual, Pub. 100-04, Chapter 17. The ASP methodology uses quarterly drug pricing data submitted to the CMS by drug manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis.

93. Starting in January 2006, Part D of the Medicare Program provided subsidized drug coverage for all Medicare beneficiaries, with low-income individuals receiving the greatest subsidies. Questcor has targeted Medicare Part D

beneficiaries for sales of H.P. Acthar Gel, including for off-label uses, by, among other things, assigning national account staff to ensure that H.P. Acthar Gel would be reimbursed. On occasion, Relator Strunck was required to work directly with Questcor's Associate Director for Specialty Distribution and Payer Relations, Jason Camp.

94. During the time period relevant to this Complaint, Questcor promoted off label uses of H.P. Acthar Gel that were not eligible for reimbursement from Medicare because the dosage that Questcor encouraged healthcare providers to prescribe was neither listed in the FDA approved labeling nor included in any of the drug compendia specified by the statute.

VIII. BACKGROUND AND APPROVAL OF H.P. ACTHAR GEL

95. Acthar (corticotrophin) was a brand-name drug that was developed by the company now known as Sanofi-Aventis, and that was first approved by the U.S. Food and Drug Administration (FDA) in 1950. H.P. Acthar Gel is a different, albeit related, drug that also was developed by Sanofi-Aventis, and that was first approved by the FDA in 1952. Questcor acquired the rights to both Acthar and H.P. Acthar Gel in 2001.

96. H.P. Acthar Gel is an injectable drug. It is a 39-amino-acid peptide natural form of adrenocorticotropic hormone (ACTH). It works by stimulating the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a few other

weakly androgenic substances. Thus, H.P. Acthar Gel is an adrenocorticotropic hormone (ACTH) analogue.

97. Upon acquiring Acthar and H.P. Acthar Gel from Sanofi-Aventis in 2001, Questcor applied for "Orphan Drug" designation for H.P. Acthar Gel for the treatment of Infantile Spasms (a very rare medical condition that affects fewer than 20,000 infants in the United States). That application was approved on May 21, 2003, but with an exclusivity start date of October 15, 2010 (the date the FDA approved H.P. Acthar Gel for the treatment of Infantile Spasms). Although orphan drug status is limited to the indication for which it was granted (Infantile Spasms), the marketing exclusivity afforded by orphan drug status (i.e., the seven-year period during which the FDA will not approve any other ACTH formulation for the treatment of Infantile Spasms) has provided Questcor with significant pricing protection for H.P.Acthar Gel, generally.

A. FDA Approval of H.P. Acthar Gel

98. The FDA approved H.P. Acthar Gel on April 29, 1952 for multiple indications, and the approval was expanded to include multiple sclerosis (MS) in 1972. In 2010, the FDA provided additional approval for the treatment of infantile spasms in pediatric patients (IS). Thus, today, H.P. Acthar Gel is approved by the FDA for the following indications:

(i) as monotherapy for the treatment of IS in infants and children under two years of age;

(ii) for the treatment of acute exacerbations of MS in adults;

(iii) as adjunctive therapy for short-term administration in various rheumatic disorders;

(iv) during an exacerbation or as maintenance therapy in cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis) (two collagen diseases);

(v) for severe erythema multiforme or Stevens-Johnson syndrome (two dermatologic diseases);

(vi) for serum sickness;

(vii) for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa;

(viii) for symptomatic sarcoidosis; and

(ix) to induce a dieresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

However, substantially all of Questcor's net sales are generated from just three of those indications: (i) acute exacerbations of MS in adults; (ii) nephrotic syndrome (NS); and (iii) infantile spasms.

99. H.P. Acthar Gel is a dangerous drug with wide-ranging and potentially life threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking H.P. Acthar Gel may suffer:

(i) increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms of infection may be masked;

(ii) adrenal insufficiency

(iii) Cushing's Syndrome

(iv) elevated blood pressure;

(v) masking of symptoms of other underlying diseases and disorders;

(vi) gastrointestinal perforation and bleeding;

(vii) behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;

(viii) comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;

(ix) ophthalmic effects, such as cataracts, infections and glaucoma;

(x) loss of endogenous activity

(xi) enhanced hypothyroidism or liver cirrhosis for patients already suffering from those conditions;

(xii) negative effects on pediatric growth and physical development;

(xiii) decrease in bone density; and

(xiv) potential fetal harm in patients who are pregnant.

100. Additionally, the FDA-approved label warns that patients taking immuno suppressive doses of H.P. Acthar Gel should not be administered live or attenuated vaccines,

101. In view of H.P. Acthar Gel's unusual safety profile, the FDA took the additional, non-standard step when it approved H.P. Acthar Gel for the treatment of IS of also approving a Risk Evaluation and Mitigation Strategy (RAMS) that requires Questcor to distribute an approved Medication Guide with each prescription, and also to submit RAMS Assessments to the FDA at periodic intervals following approval of the RAMS. The approved Medication Guide elaborates on the serious and significant side effects associated with H.P, Acthar Gel.

B. Compendium Approval of H.P. Acthar Gel

102. Congress has adopted a compendia-based system for determining appropriate reimbursements for off-label uses of a "covered outpatient drug." *See Social Security Act §§ 1927(g)(1)(B)(i) and (k)(6).* The statute permits reimbursements for drug uses that *"(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results."* The only way a prescription for an off-label use could be reimbursed under Medicare or the other Government Programs is if the particular off-label use was has been recommended by one of the compendia identified in the statute, Social Security Act, such a recommendation qualifying the use as a "medically accepted indication." *Id.*

103. There are only three compendia supported uses for H.P. Acthar Gel beyond its FDA-approved label:

i. DRUGDEX supports the use of H.P. Acthar Gel for the treatment of adrenal insufficiency in adult and pediatric patients. This is a Class Ha recommendation.

ii. DRUGDEX supports the use of H.P. Acthar Gel for the treatment of gout in adult patients. This is a Class 11b recommendation.

iii. The AHFS compendium supports the use of H.P. Acthar Gel for the treatment of active, moderate to severe, Crohn's Disease.

C. Questcor's Predatory Pricing of H.P. Acthar Gel

1. Questcor Used Orphan Drug Status To Dramatically Increase Price

104. In August 2007, in anticipation of receiving FDA approval of an indication for H.P. Acthar Gel to treat infantile spasms, Questcor announced a new business model and pricing strategy for H.P. Acthar Gel. This new pricing strategy increased the cost of H.P. Acthar Gel from approximately $1,600 per vial to approximately $23,000 per vial. This increased the cost of a typical course of treatment for Infantile Spasms from approximately $6,400 to $92,000, and it increased the cost of the FDA-recommended course of treatment for acute exacerbations of MS from approximately $7,000 to $100,000 or more.

105. Questcor was able to make this change because orphan drug status precluded the FDA from approving another ACTH formulation for seven years,

unless the other formulation were demonstrated to be clinically superior to H.P. Acthar Gel - a very high bar. As a practical matter, this precluded the FDA from approving another ACTH formulation for any purpose, thus providing Questcor with market exclusivity.

106. Market exclusivity provided substantial protection against downward pricing pressure from similar drugs, because the FDA could not approve any similar drugs. However, it created significant pressure for Questcor to distinguish H.P. Acthar Gel from the much cheaper and widely-preferred Solu-Medrol for acute exacerbations of MS, which remained the predominant intended use of H.P. Acthar Gel. (Solu-Medrol is not precluded by H.P. Acthar Gel's orphan drug status because it is not a formulation of ACTH and is not indicated for the treatment of infantile spasms.) This pricing pressure, combined with the fact that Solu-Medrol is approved for a substantially shorter course of treatment than H.P. Acthar Gel for acute exacerbations of MS, provided the impetus for Questcor's Fraudulent Marketing Scheme, described infra.

107. The implementation of this new pricing strategy also included a change in the method of distribution for H.P. Acthar Gel from multiple distributors to a single specialty distributor, CuraScript Specialty Distribution, Inc. ("CuraScript"). In August 2007 Questcor elected to stop selling Acthar to wholesalers and its sole distributor of the drug became CuraScript. Simultaneously, the average wholesale price of the same 5 ml vial increased to $29,086.25. In summary, Questcor sells H. P. Acthar Gel at a discount from its list price to

CuraScript, which then resells the H.P. Acthar Gel primarily to approximately twelve specialty pharmacies and to children's hospitals.

108. Effective January 1, 2011, Questcor's price to sell H.P. Acthar Gel to CuraScript was $24,195 per vial. Each vial is a 5ML multi-dose vial that includes 80 units/ML of the drug. As discussed below, that is enough drug for a five-day course of treatment. The cost has continued to increase dramatically and is now over $38,000.00 per vial.

109. At all relevant times, Questcor has known that H.P. Acthar Gel is being paid for or reimbursed by Government Programs, including Medicare Part D, TRICARE and the Veterans Administration - all of which generate net sales for the company. Although Questcor has since January 1, 2011 paid a Medicare rebate for H.P. Acthar Gel under the Patient Protection and Affordable Care Act of 2010 and the Healthcare and Education Affordability Reconciliation Act of 2010, the company estimates that rebate is less than ten percent of the price of the drug.

2. Questcor Implemented a Fraudulent Marketing Scheme to Increase Sales and Reimbursements of H.P. Acthar Gel.

110. When Questcor implemented its predatory price increase for H.P. Acthar Gel in 2007, Questcor understood that the primary clinical use for the drug was for the treatment of acute exacerbations of MS, and that financial success hinged on the company's ability to persuade physicians to prescribe the drug in lieu of its primary competitor drug, Solu-Medrol.

111. Questcor knew it faced a daunting task because (i) physicians considered Solu -Medrol to be the *"gold standard"* for acute exacerbations of MS; (ii) Solu-Medrol required only a five-day course of treatment, as opposed to the two to three week course approved indication by the FDA for H.P. Acthar Gel; and (iii) at approximately $1,200, a single course of treatment with Solu-Medrol was far less expensive than the $100,000 or more that a full, FDA-recommended two to three week course of treatment with H.P. Acthar Gel would cost. Questcor's Fraudulent Marketing Scheme was designed and intended to meet this challenge.

112. Beginning at least as early as 2007, Questcor designed its Fraudulent Marketing Scheme to increase sales of H.P. Acthar Gel by (i) promoting H.P. Acthar Gel for unapproved doses and indications in order to more effectively compete against Solu-Medrol for treatment of acute exacerbations of MS; and (ii) inducing doctors to promote and prescribe H.P. Acthar Gel by providing them with things of value.

113. Questcor knows, or it has been reasonably foreseeable to Questcor, that its promotion of H.P. Acthar Gel leads to the submission by physicians, specialty pharmacies and government-funded health plans of prescriptions that are ineligible for payment by Government Programs.

114. By way of example, on June 3, 2011, Regional Manager Ken Miller circulated an email to his sales specialists that recommended they follow certain enumerated strategies (developed by sales specialist Allison Polich) for persuading medical practices to prescribe H.P. Acthar Gel for their patients who are Medicare

beneficiaries. As a result by way of example, during the third quarter of 2011, Questcor shipped 2,910 vials of Acthar, up 54% compared to 1,890 vials in the year ago quarter.

115. When Questcor initially decided to employ the illegal practices described herein, it knew or should have known that physicians, specialty pharmacies and federally-funded health programs would routinely and necessarily file claims with Government Programs for reimbursement for H.P. Acthar Gel prescriptions. But for Questcor's illegal promotion, these prescriptions for H.P. Acthar Gel would not have been written, or they would not have been paid or reimbursed by Government Programs. As a result, Questcor has caused, and continues to cause, the submission of false claims to Government Programs for reimbursement of H.P. Acthar Gel. Questcor has been the beneficiary of these false claims for reimbursement of H.P. Acthar Gel prescriptions.

IX. Questcor Illegally Promotes and Markets H.P. Acthar Gel for Off-Label Use.

A. Questcor Promotes H.P. Acthar Gel For Unapproved Five Day Dosage Through False, Misleading and Deceptive Practices.

116. The FDA-approved label for H.P. Acthar Gel recommends a two to three week course of treatment for acute exacerbations of MS because that is the only protocol for which there is any reliable scientific data demonstrating both efficacy and relative safety.

117. However, Questcor recognized as early as 2007 that promoting H.P. Acthar Gel for a two to three week course of treatment would be a non-starter for

most physicians, since Solu-Medrol was equally effective, much less expensive, and required only a five-day course of treatment.

118. Thus, the starting point of Questcor's promotional strategy was a decision to proactively promote and market H.P. Acthar Gel for a one week (five-day) course of treatment instead of the two to three week course designated in its FDA-approved label, Indeed, Questcor's own slide-decks for its March 2011 and September 2011 Investor Relations Conferences described the MS dosing period as "1-2 weeks." See Exhibit B attached hereto, NASDAQ: QCOR, March 2011, page 10.

119. Questcor made this decision, and implemented this sales strategy, despite the fact that the only data regarding the safety and efficacy of a five-day course of treatment is anecdotal evidence of a Questcor-sponsored investigation conducted by Dr. Stanley A. Brod that has not been published and did not follow necessary clinical guidelines. (hereafter, the "Brod Protocol"). A copy of the Brod Protocol is attached hereto as Exhibit C. Not coincidentally, Dr. Brod is Questcor's most highly paid promotional speaker. Moreover, Questcor failed to disclose use of the Brod Protocol to the FDA as required by 21 C.F.R. § 314.81(b)(3)(i) and the submission of FDA Form 2253. Questcor did this knowing full well the significant safety risks that are associated with taking H.P. Achtar Gel (see ¶¶ 99 - 101)

120. During initial sales training in 2010, during national sales meetings, and during field training with Regional Managers, Questcor and then Mallinckrodt after the merger, and to the present consistently tells its sales specialists that they should promote H.P. Acthar Gel for a five-day course of treatment (without even

mentioning the broader language in the drug's FDA-approved label) because that was the only way they could compete effectively against Solu-Medrol. This was referred to as the "Brod Plan." Attached hereto as Exhibit D is a copy of a Power Point presentation used by Questcor for training with its sales force. On page 5 of the Presentation under the caption "The New MS Plan" it, inter alia, directs the sales force to use the *"Brod Plan,"* e.g., market the H.P Achtar Gel as a five day dosing regimen. Questcor failed to disclose use of the Plan to the FDA as required by 21 C.F.R. § 314.81(b)(3)(I) and the submission of FDA Form 2253.

121. On April 20, 2011, Relator Strunck's immediate supervisor, Regional Manager Ken Miller, specifically told him both verbally and via email that he should speak with co-relator Lisa Pratta, a successful sales specialist in New Jersey, to learn how she was promoting the five-day Brod protocol so that he could incorporate her techniques into his own sales process.

122. Questcor training of sales representatives to promote and market the five day dosing continued through 2013 by using Power Point slides[10] used for training speakers. In particular, please note slide #5 regarding "Achtar Dosing in MS" which, after stating the label dosing, continues with the following guidance:

- *"Dosage should be **individualized according to the medical condition** of each patient"*

[10] See Attached Exhibit E - Achtar Speaker Training, see slide 5

- *"Dosing frequency should be determined according to the severity of the disease and the initial response of the patient"*

There is an important and critical distinction between this language and the Label. The FDA Label[11], under DOSAGE AND ADMINISTRATION states as follows:

. . . .

- **In the treatment of acute exacerbations of multiple sclerosis**, daily intramuscular or subcutaneous doses of 80 -120 units for 2 - 3 weeks may be administered. It may be necessary to taper the dose. (2.2).

- **In the treatment of other disorders and diseases**, dosing will need to be *individualized depending on the disease under treatment and the medical condition of the patient.* It may be necessary to taper the dose (2.3)

Questcor failed to disclose use of these slides to the FDA as required by 21 C.F.R. § 314.81(b)(3)(i) and the submission of FDA Form 2253.

123. By comparing the dosing in MS training slide to the dosing guidelines on the Label for MS and *"other disorders and diseases"*, it is clear that Questcor is training speakers to promote dosing for MS contrary to the label. Specifically, Questcor has taken the "Dosing and Administration" labeling for *"other disorders and diseases"* [see above] and transposed it for training purposes into the labeling

[11] A copy of the approved FDA Label is included herein at the back of Exhibit A

for *"treatment of acute exacerbations of multiple sclerosis."* This can only be interpreted as a direct promotional statement contrary to the labeling for treatment of acute exacerbations of multiple sclerosis. It is clear that they are attempting to take advantage of the non-specific dosing regimen for that is part of the label for *"other disorders and diseases"* and make it part of the dosing for *"treatment of acute exacerbations of multiple sclerosis."*

124. Questcor also directly promoted off-label five day dosing through presentation of misleading comparative studies performed by Questcor employees. Attached hereto as Exhibit F is an "in house" study used as a sales tool entitled *"A Comparison of the Safety/Tolerability and Pharmacodynamics of Achtar Gel and Methylprednisolone With Regimens Utilized For The Treatment of MS Exacerbations"* (herein, the "Study" or "Marketing Brochure"). This Marketing Brochure is a clear and brazen example of illegal off-label promotion that has caused the submission of false claims in the following manner:

A. In the INTRODUCTION section, Questcor states that Achtar and intravenous methylprednisolone (IVMP) *"are both utilized to treat multiple sclerosis (MS)."* While this may be true for IVMP, H.P. Achtar Gel is only indicated for "acute exacerbations." This is clearly an attempt to promote H. P. Achtar Gel for the progressive form of MS through "pulse therapy."

B. Also, in the INTRODUCTION section, Questcor represents that the dosing regimen used (5 days) in the Study, is a *"dosing regimen for both of the drugs that have been commonly employed for treatment of MS exacerbations."*

While this may be true for IVMP, H. P. Achtar Gel is only indicated for a dosing regimen of 2-3 weeks. If a dosing regimen of 5 days has become *"commonly employed"* for Achtar it can only be attributed to Questcor's massive off label marketing promotion.

C. The Study clearly uses a dosing regimen of 5 days without any of the safeguards required by the FDA for a clinically sound study. According to the FDA, the statutory requirement that a drug's effectiveness be demonstrated by *"adequate and well-controlled clinical investigations"* has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. *21 C.F.R. § 314.26.* The Study outlined in this Marketing Brochure fails to meet this standard for multiple reasons as follows:

1. It has not been accepted for publication by a reputable neurology journal.

2. It contains a very small sampling of patients which would not be acceptable to the FDA because it would not qualify to show statistical significance.

3. The poster only deals with the measurement of cortisol levels of patients after they had both Acthar and solu-medrol even though Questcor management knows that it is not a measure of efficacy between the two drugs. It is

solely intended for the sales force to use it as an example to sell 5 day dosing and also to make a comparison of H. P. Acthar Gel to IVMP in efficacy and side effects.

4. A clinically sound study would have had at least 100 patients and would also be a double blind study which means the groups did not know which drug they were taking. Here the patients knew which medication they were taking.

5. The comparison study set forth and described in the Marketing Brochure was done by Questcor employees and is based on a dosing regimen of 80 U/ml for 5 days.

Moreover, Questcor failed to disclose use of the Marketing Brochure to the FDA as required by 21 C.F.R. § 314.81(b)(3)(I) and the submission of FDA Form 2253.

B. Questcor Promotes H.P. Acthar Gel Five Day Dosing For Unapproved Indication of "Progressive" MS Through Pulse Therapy

125. According to the FDA Approved Label, H. P. Acthar Gel is only indicated for use for"acute" exacerbations of MS. There are four classes of MS. Most patients have the form of relapsing-remitting MS. The other three types of MS are a progressive form, which means the patients are in a constant declining exacerbation. These three types of MS patients are not indicated for Acthar because they are not having acute relapses.

126. Neurologists have used "pulse therapy" on their progressive patients with solu medrol for many years. Pulse therapy is a term used for monthly use or infusion of a drug on a prophylactic type basis. Even though H. P. Acthar Gel is not indicated for this use and condition, Questcor and their sales reps have been promoting this use to physicians.

127. Questcor is promoting the 5 day course of therapy (1 vial) to be used on these "progressive" MS patients once a month. Because insurance companies, Medicaid and Medicare will not pay for an off label use of H. P. Acthar Gel, sales representative have been and are instructed to *"pre-populate"* on the written Referral Form that the patient is in an "acute" exacerbation. This is done by indicating on the left hand side of referral on the bottom the ICD-9 diagnosis code "340" which means "acute." (See Exhibit H)

128. An example of this practice is the Referral Form (attached hereto as Exhibit H) for Amos Katz, MD. This was done by Joe Citkowski, Relator Pratta's KOL (Key Opinion Leader) who told Pratta that she *"should fill this in on the forms for them."* Citkowski also did this for Dr. Terrance MacAlarney and Dr. Caren Marks who are part of the same practice as Dr. Amos Katz. The form has been pre-populated with *"80 units once/day for 5 consecutive days."* This was done and given to Dr. Katz's nurse (Rita) so that she would have a "model form" to follow. Citkowski is a KOL Sales Representative and Citkowski advised Pratta that this practice is being repeated elsewhere by other representatives and is not an isolated instance. This was done by Citkowski sometime between June 11, 2013 and August

2, 2013 when Relator Pratta learned about it at a lunch meeting with Dr. Katz and Citkowski.

129. This practice is continuing but Questcor has changed the Referral Form. A copy of the new Form is attached as Exhibit I. On page 3 of the new form, there is a "DIAGNOSIS AND MEDICAL INFORMATION" section. One of the questions is related to the type of MS the patient has as follows:

. . .

❑ **Multiple Sclerosis**

Is Achtar to be used to treat an acute exacerbation ❑ **yes** ❑ **no**

. . .

Joe Citkowski, Lisa's KOL (Key Opinion Leader), who has been pre-filling the "acute" designation of "#340" on the old form, advised Pratta on March 10, 2014 that, with respect to the new referral form, he is *"going to pre fill in the form"* and *"check off the box for acute for his other offices."*

130. In the Fall of 2016, Relator Pratta was assigned to a new reimbursement manager. His name is Jonathan Rosser, who joined Defendant in early 2015. Rosser handles all divisions: Neurology, Rheumatology, Pulmonology, and Nephrology. Mr. Rosser told Relator Pratta on the phone on October 28, 2016 that representatives from all divisions are *filling out the referral forms* [i.e. forms referred to above] *and are writing letters of medical necessity for their physicians.*

131. Questcor sales representatives were being encouraged to promote "pulse therapy" which means writing a prescription for three (3) vials to be used once a

month. One of the ways Defendant enabled this was to have sales representatives suggest that physicians need to diagnosis the patient with "active flow." Stacy Clancy, at the direction of Mike Zorzy, and Corey Prado, at the direction of Ken Miller are examples of where Relator is aware this is occurring. At the end of the three month period, a new prescription is written for three vials for another three months.

132. As a follow up to this, Christine Traficant, who is a sales representative in Relator Pratta's region, told her at the AAN meeting in San Diego on March 13, 2013, that the new pulse therapy dosing promotion[12] went over *"really well at the meeting."* Specifically, one of her physicians, (Dr. Charles) who was there stated that he was going to begin to use Acthar for pulse therapy. John Stabile, her manager said that *"Christine was probably now be seeing plenty of "pulse" business."* A copy of the promotion presented at the AAN Meeting in San Diego is attached hereto as Exhibit J. The Abstract suggested a benefit for H.P. Achtar Gel using monthly pulse therapy but acknowledges that "*further studies, including randomized controlled trials are needed to validate the findings."*

133. Questcor sales representatives are also telling the neurologists to write for one vial and add three refills, so it does not appear as a pulse therapy use for the patient. Questcor was paying their sales reps for these monthly referrals for the pulse therapy use for the same patient, but in the February 2013 National Sales meeting, announced that reps will only be paid for one referral each quarter so it does not look like they are paying reps bonus for "off label" use. Stacy Clancy, a neurology sales

[12] See Exhibit J. Abstract released at AAN Meeting on March 10, 2013. .

representative, in a conversation that occurred on or about April 12, 2013 learned from Nick Brunetti (Questcor's Number 1 Sales Rep for Acthar MS) that *"all of his business was for monthly pulse therapy."*

134. KOL Sales Representative Joe Citkowski is one of the primary reps who pursues this strategy and gets the majority of the credit for them. Some of the Physician/Sales Representatives include:

Physician	Sales Representative
Ruth Brobst MD	Stacy Clancy
Susan A. Gaulthier MD NY,	James Worsham
Derek Smith MD	Ted Medru
Tim Vartanian MD NY	James Worsham
Johnathan Howard MD	James Worsham
Robert Knobler MD	Stacey Clancy
Jason Silverstein MD	Bob Bobeck

C. Defendant Is Promoting Five Day Dosing of Achtar as "indicated" for "First Line Use."

135. Achtar sales representatives are now being directed to market and promote Achtar as a "first line" use despite the fact that all Government Health Care Programs (and others) have consistently required prior to authorization and certification that the MS patient is (i) being treated with a relapsing remitting multiple sclerosis agent (e.g., Avonex, Betaseron, Copaxone, Gilenya) *AND* there is a failure or clinically significant adverse effects to corticosteroid therapy for acute exacerbations of multiple sclerosis.

136. There is no published, peer reviewed article, material, finding or study considered *"scientifically sound"* by experts that supports the use of H. P. Achtar Gel as a first line use for MS. This renders these prescriptions as "off-label" and "medically unnecessary."

137. Specifically, as part of it's new business plan instituted in the Fall of 2016, sales representatives are being directed to complete physician profile sheets (PPS) that were designed and sent out by the VP of Neurology, Kyle Jennings. This practice is further confirmed by the individual Physician profiles that each representative is asked to complete for their respective physicians. See Exhibit K[13].

138. On page 5 of the PPS (Exhibit K), the sales representative is directed to answer the following question:

Does the physician understand ACHTAR is indicated first line in relapse?

This is being used as a follow up the sales division to make sure the message about first line use is being conveyed.

D. Questcor Misused Medical Information Request Forms (MIRFs) As a Way of Promoting and Marketing the Five Day Dosing and Pulse Therapy

139. Another way in which Questcor promoted this off-label dosage of H.P. Acthar Gel was through its use of Medical Information Request Forms ("MIRFs"). A

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[13] The PPS attached hereto is one from Taiman Zaman, MD, a physician that Relator Lisa Pratta calls on. As you will note, Pratta responded by stating *"Achtar is not first line"* and advised her superiors in writing of this on December 6, 2016. In late January she was advised that her territory is being restructured and is being terminated. However, she has been informed that sales representatives are being directed to promote Achtar in this manner and the PPS is being used to corroborate that it is being done.